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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61F 2/06

A1

(11) International Publication Number: WO 92/16166

(43) International Publication Date: 1 October 1992 (01.10.92)

(21) International Application Number: PCT/GB92/00538

(22) International Filing Date: 24 March 1992 (24.03.92)

(30) Priority data:

9106347.9	25 March 1991 (25.03.91)	GB
9206282.7	23 March 1992 (23.03.92)	GB

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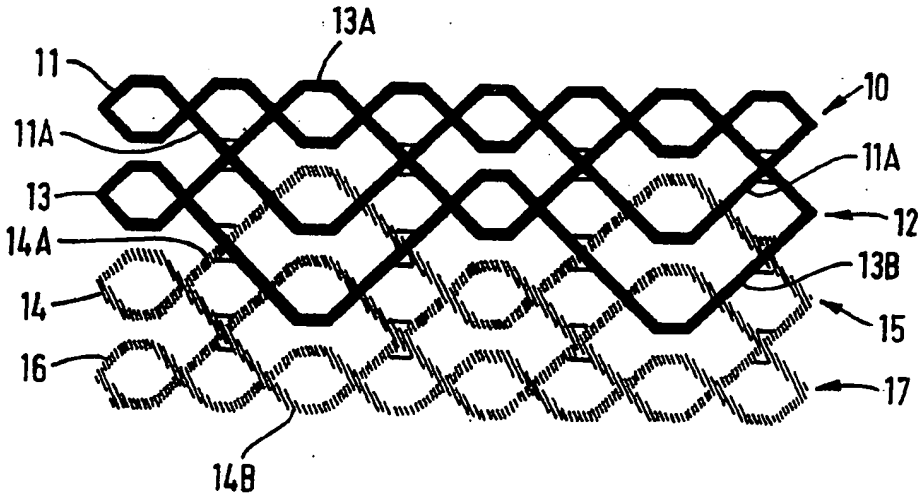
(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CI (OAPI patent), CM (OAPI patent), CS, DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GN (OAPI patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC (European patent), MG, ML (OAPI patent), MN, MR (OAPI patent), MW, NL, NL (European patent), NO, PL, RO, RU, SD, SE, SE (European patent), SN (OAPI patent), TD (OAPI patent), TG (OAPI patent), US.

Published
With international search report.

(54) Title: VASCULAR PROSTHESIS



(57) Abstract

The present invention provides a vascular prosthesis which comprises a braided tubular fabric comprising a plurality of braid layers wherein each layer includes at least one interlocking yarn which extends from that layer into another layer to form an interlock therewith. In one aspect of the invention, the plurality of braid layers may include a substantially non-absorbable first surface layer and a substantially resorbable second surface layer.

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DESCRIPTION

VASCULAR PROSTHESIS

The present invention relates to a vascular prosthesis.

In surgery, tubular vascular prostheses are typically used for the replacement of damaged or worn-out blood vessels. Such a prosthesis should desirably have properties of radial and longitudinal elasticity which resemble closely the corresponding properties of natural blood vessels, thereby to avoid aneurysm at the anastomosis and to maintain patency of the implant. Further, it is desirable that a synthetic vascular prosthesis should allow tissue ingrowth to form a smooth, non-thrombotic endothelium of natural cellular tissue. It will be appreciated, therefore, that after implantation the prosthesis should provide a porous support structure which gives the implant an intrinsic strength matching the strength of a natural blood vessel and allows cellular growth to invade the prosthesis to form a neointimal vessel lining having an organised cell structure. However, immediately on implantation the prosthesis is desirably impermeable

to blood, thereby to avoid bleeding without the requirement for preclotting which hinders tissue ingrowth and promotes thrombosis.

A typical tubular vascular prosthesis comprises a tubular fabric which includes a resorbable yarn component, and a non-absorbable yarn component. The yarns are incorporated in the fabric to form a prosthesis which is initially impermeable to blood and, over a period of time following implantation, the biologically absorbable fibres are resorbed, thereby increasing progressively the porosity of the prosthesis to allow ingrowth.

Hitherto, synthetic vascular prostheses have been made by weaving, braiding, knitting or crochetting, but tubular vascular prostheses made of synthetic fibre yarns by weaving or knitting are not suitable for use when the diameter of the prosthesis is less than about 6mm. Problems such as kinking and anastomotic hyperplasia at the interface between a natural artery or vein and such a tubular prosthesis prevent the use of such a graft having an internal diameter of less than 6mm.

European Patent Specification No. A0397500 discloses a vascular prosthesis which is formed by weaving, knitting or braiding a synthetic semi-absorbable composite yarn to form a tubular fabric. The composite yarn comprises a non-absorbable elastic core which imparts resiliency to the composite yarn and an absorbable, relatively inelastic sheath which imparts transverse tensile strength to the composite yarn. In use, the sheath material is progressively resorbed, whereby a porous structure develops which provides a scaffold for tissue ingrowth and exhibits structural properties resembling the dynamic fluid pressure response characteristics of natural vascular tissue. The vascular prosthesis of EP-A-0397500 has an initial low permeability to prevent blood leakage in pre-heparinized patients without the requirement for pre-clotting and an increasing permeability in use to allow the progressive development of a smooth, non-thrombogenic neointima. However, the intrinsic structural characteristics of the prosthesis change as the sheath material is eroded. The graft, therefore, is not satisfactory unless the erosion of the sheath is matched by tissue ingrowth to maintain the strength of the prosthesis.

According to one aspect of the present invention there is provided a vascular prosthesis which comprises a braided tubular fabric comprising a plurality of braid layers wherein each layer includes at least one interlocking yarn which extends from that layer into another layer to form an interlock therewith.

In another aspect of the present invention, the plurality of braid layers may comprise a substantially non-absorbable first surface layer and a substantially resorbable second surface layer.

The braided tubular fabric may be formed by interbraiding one yarn of a non-resorbable material with another yarn of a biologically resorbable material. The first surface layer may be formed substantially only of said one yarn, and the second surface layer may be formed substantially only of said other yarn. Typically, the resorbable material may be selected from catgut (collagen sutures derived from sheep intestinal submucosa), reconstituted collagen, polyglycolic acid (PGA) and its lactide copolymers, polydioxanone (PDS) and poly(glycolide-trimethylene carbonate). The non-absorbable material may be

selected from natural fibres such, for example, as silk and cotton and synthetic fibres such, for example, as polyethylene, polypropylene, polyamide, polyester, polytetrafluoroethylene and stainless steel.

According to one aspect the outer surface layer of the fabric is substantially non-absorbable, and the inner or luminal surface layer is substantially resorbable. The fabric may also comprise one or more intermediate layers between said surface layers. Each intermediate layer may be formed of said two yarns interbraided with one another. The proportion of said one yarn in each layer may decrease progressively, and the proportion of said other yarn in each layer may increase progressively from one of said surface layers to the other surface layer.

According to a particular aspect of the invention, the diameter of the tubular braided prosthesis may be about 6mm or less; although the invention also comprehends prostheses having diameters greater than 6mm.

In some embodiments, the tubular fabric may include non-absorbable, external support means. The said support means may comprise at least one wrap which follows a helical or spiral path around the exterior of the fabric; and in one aspect the support means includes two wraps, each wrap following a spiral path of opposite handedness to the other wrap.

Each wrap may be formed of an elongate textile structure having a suitably high bending modulus or stiffness. According to some embodiments, each wrap comprises a monofilament or yarn having a high denier. Alternatively, the wrap may be a multifilament yarn or braid formed of a plurality of strands having a high composite denier and a linear density greater than that of the braided tubular fabric.

The wrap may be attached to the external surface of the fabric by any suitable adhesive or by heating to form fibre-to-fibre bonds. Preferably, however, each wrap is incorporated into one or more of the intermediate or external surface layers of the braid forming the fabric. In a particular aspect of the invention, the wrap may be incorporated in the braid

structure of the said external surface layer to follow a helical path; more particularly, the said wrap may be incorporated in the braided external surface layer such that it does not form an interlock with any of the other braid layers. The wrap(s) may be formed of any suitable non-absorbable material; in one embodiment, a polyester wrap may be utilized.

A suitable method and apparatus for forming a tubular braided fabric for use as a vascular prosthesis in accordance with the present invention is disclosed in the specification as published under International Patent Publication No. WO91/10766, the disclosure of which is incorporated herein by reference. According to this method, a braided fabric comprising a plurality of interlocked layers is produced by a plurality of package carriers of yarn which are constrained by track module means to move along a plurality of serpentine paths; the track module means being arranged to extend in a first direction to define a longitudinally extending path corresponding to a first layer of the braided fabric and in a second direction to provide at least one cross-over path between adjacent serpentine paths. The package

carriers are moved in said first direction to create a first layer of braid and along a cross-over path between adjacent serpentine paths to cause the yarn forming said first layer of braid to be transported to interlock with the braid of an adjacent layer.

The apparatus for the production of such a braided fabric comprises: a two-dimensional array of rotatable horn gears in toothed engagement; driving means for driving said array, each horn gear being arranged to rotate in a direction contrary to each interengaging gear; track means overlaying said array; and a plurality of yarn package carriers movable along said track means by said horn gears. The track means comprises a plurality of track modules which together define a plurality of serpentine paths extending in a first direction, each serpentine path corresponding to a braid layer in said fabric and in which selected track modules include at least one cross-over path section extending in a second direction between one serpentine path and the next adjacent serpentine path to cause or allow the package carriers to move between adjacent serpentine paths to

effect interbraiding of yarns between adjacent layers.

A base bed may be provided on which a plurality of gear modules may be arranged in an infinite array, and over which the track modules may be positioned. The base bed may be disposed in a cylinder and provides a tubular multilayer tubular braid in which the layers are interlocked or interbraided one with another.

A multi-layer braided tubular prosthesis according to the present invention may have the advantage that the structural characteristics of the fabric do not change as the resorbable material is absorbed. In use, therefore, the change in permeability of the fabric as the resorbable material is eroded may coincide with the development of a neointimal surface. Furthermore, it has been found that the use of an interlocked, multi-layer tubular braid of the type disclosed in WO91/10766 permits the production of a prosthesis having a diameter of about 6mm or less which exhibits an increased resistance to kinking as compared with known prostheses. A small diameter implant in accordance with the present invention may have

particular application as a prosthetic graft e.g. for the aorto-coronary artery or the femoral-popliteal artery.

A tubular braided fabric having interlocked layers produced by the method and apparatus of WO91/10766 may be stronger than a conventional tubular braided structure having layers which are not inter-connected. The properties of such a prosthesis tend to degrade over time, and the improved initial strength assists materially the longevity of the prosthesis. The braid prosthesis of the present invention, therefore, may be less vulnerable to kinking when bent. The relatively high radial compression resistance may minimise the effects of anastomotic hyperplasia, and the relatively low radial compliance in tension may accommodate the systolic pressure pulse.

A significant advantage of the vascular prosthesis in accordance with the present invention is that with the braided fabric the lay of the bulk of the yarns constituting the braid is at a significant angle to the longitudinal axis of the prosthesis. In the prior art methods using woven fabrics, one of the yarns of

weave usually extends in the longitudinal direction. This means that in use, bending and flexing of such woven prostheses results in much greater stress and strain on such longitudinal yarns thus resulting in kinking and sometimes premature failure of the prosthesis. The angular disposition of the yarns of the prosthesis of the present invention permits of sharp bends in the prosthesis without imparting such strain on the yarns forming the braid.

Following is a description by way of example only and with reference to the accompanying drawings of methods of carrying the present invention into effect.

In the drawings:-

Figure 1 is a schematic illustration of a cross-section of a fragment of a multi-layer braided fabric tubular prosthesis in accordance with the present invention;

Figure 2 is a graph of the radial stress strain relationship of the multi-layer braided tubular fabric of Figure 1.

Figure 3 is a schematic illustration of a braided prosthesis according to the present invention including exterior helical support means;

Figure 4 is a schematic illustration of a different supported tubular braided prosthesis in accordance with the present invention.

Figure 5 is two photomicrographs at X11 magnification which show the external surface of the supported tubular braided prosthesis of Figure 4;

Figure 6 is two photomicrographs at X12 magnification of the prosthesis of Figure 4.

Figure 7 is two photomicrographs at X20 and X25 magnification respectively of the inner surface of the prosthesis of Figure 4.

Figure 8 is two photomicrographs at X43 and X90 magnification respectively of the inner surface of the prosthesis of Figure 4.

Figure 9 is two photomicrographs at X14 and X33 magnification respectively which show a cross-sectional view of the prosthesis of Figure 4.

Figure 10 is two photomicrographs at X45 and X75 magnification respectively of the cross-section of Figure 9.

Figure 11 is a schematic illustration which shows the effect of systole on the prosthesis of Figure 4;

Figures 12, 13 and 14 are photomicrographs at X50, X50 and X15 magnification respectively which show the interior and exterior surfaces of a braided prosthesis in accordance with the present invention.

Figure 15 shows a graph of radial displacement as a function of positive radial pressure for each of six sample prosthesis in accordance with the present invention.

Example 1

In Figure 1 a fragment of a multilayer braided fabric tubular vascular prosthesis comprises four inter-locked layers (10), (12), (15) and (17). Each layer is formed by interbraiding two lengths of yarn which follow generally serpentine paths, one path superimposed on and out of phase by half a cycle with respect to the other path. Part of one of the lengths of yarn of each layer is diverted from its serpentine path to extend across to a second layer to be interbraided with one of the yarns forming that second layer; whereafter the one length of yarn is returned to its serpentine path in the first layer. In being interbraided with the yarn of the second layer, the length of yarn is passed around the yarn of the second layer so that the two layers are interlocked. In each layer the diverted portion of the one length of yarn is replaced by a similar diverted portion of yarn diverted from another layer which is interbraided with the first mentioned yarn for interlocking.

The layer (10) that forms the outer surface layer of th tubular prosthesis is formed by non-resorbable yarn material only; parts (11A) of the main length (11) of that material being diverted to interlock with one of the yarns that forms juxtaposed layer (12). In addition to the diverted portions (11A) of the yarn material (11), said juxtaposed layer (12) is formed of portions of each of other lengths (13) and (14) of yarn; length (13) also being formed of non-resorbable material, while the length (14) is formed of resorbable material.

Next juxtaposed layer (15) is formed of portions of three different yarns: yarn (14), diverted portions (13B) of the length of non-resorbable yarn (13) and diverted portions of a length of resorbable yarn (16) which forms inner surface layer (17). Inner layer (17) is also formed of diverted portions (14B) of yarn (14) which are interbraided with yarn (16).

With reference to Figure 2 the stress/strain relationship of the tubular prosthesis of Example 1 has a relatively <u>high</u> radial compression resistance and a <u>low</u> radial compliance in tension which

minimises the tendency for the prosthesis to kink and reduces the possibility of aneurysm at the anastomosis.

Example 2

With reference to Figure 3, a 5-layer interbraided tubular prosthesis (30) was made on a 6mm diameter steel mandrel using a 48-carrier braiding machine. The inner braid layer (not shown) was formed substantially of 48 yarns of resorbable 7/0 monofilament suture yarn which is commerically available from Messrs Davis & Geck under the Trade Mark MAXON: the outer braid layer was formed substantially of 46 polyester multifilament yarns of 70 denier of the type commerically available under the Trade Mark "DACRON" type 56 and 2 polyester monofilaments (32) of 0.012" diameter: and the three intermediate layers were each formed substantially of 48 yarns of 70 denier DACRON type 56.

The said polyester monofilaments (32) were incorporated into the braid structure of the outer layer to form two helical wraps in the outer surface

of the prosthesis (30); the wraps being of opposite handedness one from the other. After braiding, the prosthesis was removed from the mandrel and placed over a 5mm diameter mandrel and heat-set at 150°C for 30 minutes.

Example 3

In Figure 4, a tubular vascular prosthesis (40) was made in the same way as described in Example 2 above, but the outer braid layer was formed with only one helical wrap (42) of polyester monofilament.

Figures 5 to 10 show various photomicrographs of the prosthesis (40). In Figures 5, 6, 9 and 10 the photomicrographs show clearly the helical wrap (42) of polyester monofilament which is incorporated into the braid structure of the outer braid layer of the prosthesis (40). Wrap (42) is interbraided with the DACRON polyester multifilament yarns (44) and is not interlocked with yarns in any of the intermediate layers or inner braid layer. In Figures 7 and 8, the inner braid layer (46) of prosthesis (40) includes non-absorbable DACRON multifilament polyester yarns

(44) which are interbraided with the said resorbable MAXON suture yarns (48).

Figure 11 shows schematically the effect of cardiac systole on the prosthesis (40) which has a stress-strain relationship similar to that shown in Figure 2 in connection with Example 1 above. It will be appreciated that a tubular braid structure allows reorganisation and relative movement of the interbraided yarns to accommodate or allow changes in diameter of the tubular braid, and the low radial compliance of prosthesis (40) allows the diameter of the prosthesis (40) to expand during systole in a manner which matches closely the systolic response of natural blood vessels.

Example 4

A five-layer interbraided tubular prosthesis was made on a 6mm diameter stainless steel mandrel using a braider having 48 package carriers at a nominal braid orientation angle of 55° to the longitudinal axis of the mandrel. The inner braid layer was formed substantially of 48 resorbable, polylactic acid-based

7/0 USP suture yarns such as thos which ar commercially availabl under the Trade Mark MAXON: th next adjacent layer was formed substantially of 24 MAXON 7/0 suture yarns and 24 multifilament polyester yarns of 70 denier commercially available under the Trade Mark DACRON type 56: and the other two intermediate layers and the outer braid layer were each formed substantially of 48 DACRON type 56 yarns of 70 denier. After braiding, the prosthesis was removed from the 6mm mandrel and placed on a 5mm diameter mandrel. The prosthesis was then stretched in a longitudinal direction to cause the prosthesis to form a conformate fit to the surface of the smaller mandrel, and the mandrel/prosthesis was placed for 30 minutes in an oven heated to 150°C. After cooling the tubular prosthesis was removed from the mandrel for use.

Example 5

A tubular, five-layer braided prosthesis was prepared as described above in Example 4. The inner braid layer was formed substantially of 48 MAXON 7/0 suture yarns, and the four other layers were each formed

substantially of 48 DACRON type 56 yarns of 55 denier. Figure 6 is a photomicrograph of the surface of the outer braid layer having braided non-absorbable yarns (62). Figure 7 is a photomicrograph of the surface of the inner braid layer which comprises resorbable yarns (72) which are interbraided with yarns (74) of the next adjacent layer diverted into the inner layer to form an interlock therewith.

In Figure 8, the two surfaces are shown side-by-side for comparison.

Example 6

Six tubular prostheses (Examples 6.1 to 6.6) were made as described above under Example 4. Each prosthesis was braided onto a 6mm diameter mandrel and then transferred to a 4.75mm mandrel and heat set for 30 minutes at 150°C. In each case, the prosthesis comprised five interbraided braid layers: the inner braid layer was formed from 48 MAXON 5/0 suture yarns (except Example 6.2), and the three intermediate layers were each formed from 48 DACRON type 56 multifilament yarns, each multifilament yarn

comprising 34 monofilaments and having a total denier of 70. In the case of Example 6.2, the inner layer was formed of 48 DACRON multifilament yarns. The composition of the outer braid layer of each prosthesis was as follows:-

Prosthesis Number	Composition of Innerbraid Layer
6.1	48 DACRON type 56 (70 denier, 34 monofilament) multifilament yarns
6.2	48 DACRON type 56 (70 denier, 34 monofilament) multifilament yarns
6.3	47 DACRON type 56 (70 denier, 34 monofilament) multifilament yarns and one braided cord comprising 16 DACRON type 56 (70 denier, 34 monofilament) multifilament yarns

	6.4	46 DACRON type 56 (70 denier, 34 monofilament) multifilament yarns and two braided cords, each cord comprising 16 DACRON type 56 (70 denier, 34 monofilament) multifilament yarns.
	6.5	46 DACRON type 56 (70 denier, 34 monofilament) multifilament yarns and two 0.012 mil polyester monofilaments
	6.6	47 DACRON type 56 (70 denier, 34 monofilament) multifilament yarns and one braided cord comprising 16 interbraided DACRON type 56 (70 denier, 34 monofilament) yarns.

After heat setting, each prosthesis was cooled and removed from the 4.75mm mandrel. The radial compliance of each prosthesis was then measured by subjecting the prosthesis to internal positive pressure and measuring the radial displacement. The results of such tests are shown in Figure 15 (a) to (f) each of which shows a graph of displacement in millimetres against the outwardly directed radial pressure in mmHg for each of the six prostheses 6.1 to 6.6 respectively. In each case, the prosthesis was held under a 400g axial load, and the following table shows the threshold pressure for each prosthesis for the onset of radial displacement.

Table 1

Prosthesis Number	Onset of radial displacement/psi
6.1	250
6.2	180
6.3	410
6.4	No significant radial displacement reached
6.5	360
6.6	300

When the tubular prosthesis of the present invention is first implanted in a patient, the structure of the prosthesis provides intrinsic support. The braided prosthesis provides a graft which is initially impermeable to blood in pre-heparinized patients, but, as time progresses, the biologically resorbable material that forms the inner surface layer and parts of intermediate layers is resorbed, and body tissue is allowed to grow into interstices which are formed in the residual braided structure of non-resorbable

yarns, which structure provides a geometrically stable support.

It has been found that the stress-strain relationship of the prosthesis according to the present invention exhibits a low radial compliance and a high compression resistance which allows the prosthesis to mimic closely the properties of natural blood vessels. Further, the use of braiding technology as described in the applicant's WO91/10766 allows the provision of a tubular vascular prosthesis having a diameter of 6mm or less which is less liable to kinking and aneurysm as compared with known grafts.

CLAIMS

1. A vascular prosthesis which comprises a braided tubular fabric comprising a plurality of braid layers wherein each layer includes at least one interlocking yarn which extends from that layer into another layer to form an interlock therewith.

2. A vascular prosthesis as claimed in claim 1 wherein the said plurality of braid layers includes a substantially non-absorbable first surface layer and a substantially resorbable second surface layer.

3. A vascular prosthesis as claimed in claim 2 which is formed by interbraiding one yarn of a non-resorbable material with another yarn of a biologically resorbable material.

4. A prosthesis as claimed in claim 3 wherein the said first surface layer is formed of said one yarn, and the said second surface is formed substantially only of said other yarn.

5. A prosthesis as claimed in any of claims 2 to 4 wherein the outer surface layer is substantially non-absorbable and the inner or luminal surface layer is substantially resorbable.

6. A prosthesis as claimed in any of claims 2 to 5 wherein the fabric also comprises one or more intermediate layers between the said surface layers.

7. A prosthesis as claimed in claim 6 wherein each intermediate layer is formed of the said two yarns interbraided with one another.

8. A prosthesis as claimed in claim 6 or claim 7 wherein the proportion of said one yarn in each layer decreases progressively, and the proportion of the said other yarn in each layer increases progressively from one of said surface layers to the other surface layers.

9. A prosthesis as claimed in any preceeding claim wherein the diameter of the tubular braid prosthesis is 6mm or less.

10. A prosthesis as claimed in any preceeding claim wherein the tubular fabric includes non-absorbable, external support means.

11. A prosthesis as claimed in claim 10 wherein the said support means comprises at least one wrap which froms a helical or spiral path around the exterior of the fabric.

12. A prosthesis as claimed in claim 10 or claim 11 wherein the support means includes two wraps, each wrap following a spiral path of opposite handedness to the other wrap.

13. A prosthesis as claimed in claim 11 or claim 12 wherein each wrap is formed of an elongate textile structure having a suitably high bending modulus or stiffness.

14. A prosthesis as claimed in any of claims 11 - 13 wherein each wrap comprises a monofilament yarn having high denier.

15. A prosthesis as claimed in any of claims 11 - 13 wherein ach wrap is a multifilament yarn or braid formed from a plurality of strands and having a high composite denier and linear density greater than that of the interbraided tubular fabric.

16. A prosthesis as claimed in any of claims 11 - 15 wherein each wrap is attached to the external surface of the fabric by any suitable adhesive or by heating to form fibre-to-fibre bonds.

17. A prosthesis as claimed in any of claims 11 - 15 wherein each wrap is incorporated into one or more of the intermediate or external surface layers of the braided fabric.

18. A prosthesis as claimed in any of claims 11 - 15 wherein each wrap is incorporated in the braid structure of the said external surface to follow a helical path.

19. A prosthesis as claimed in any of claims 11 - 18 wherein each wrap is formed of a non-absorbable material.

20. A prosthesis as claimed in any of claims 11 - 19 wherein the said wrap is formed of a polyester.

21. A vascular prosthesis as claimed in the proceeding claim, which prosthesis is formed in accordance with the method the subject of International Patent Publication No. W091/10766.

22. A method performing a tubular vascular prosthesis as claimed in any preceeding claim, whereby a braided fabric comprising a plurality of interlock layers is produced by a plurality of package carriers of yarn which are constrained by track module means to move along a plurality of serpentine paths; the track module means been arranged to extend in a first direction to define a longitudinally extending path corresponding to a first layer of the braided fabric and in a second direction to provide at least one cross over path between adjacent serpentine paths; the package carriers being moved in the said first direction to create a first layer of braid and along a cross-over path between adjacent serpentine paths to cause the yarn forming the said first layer of braid

to be transported to interlock with the braid of an adjacent layer.

FIG. 1

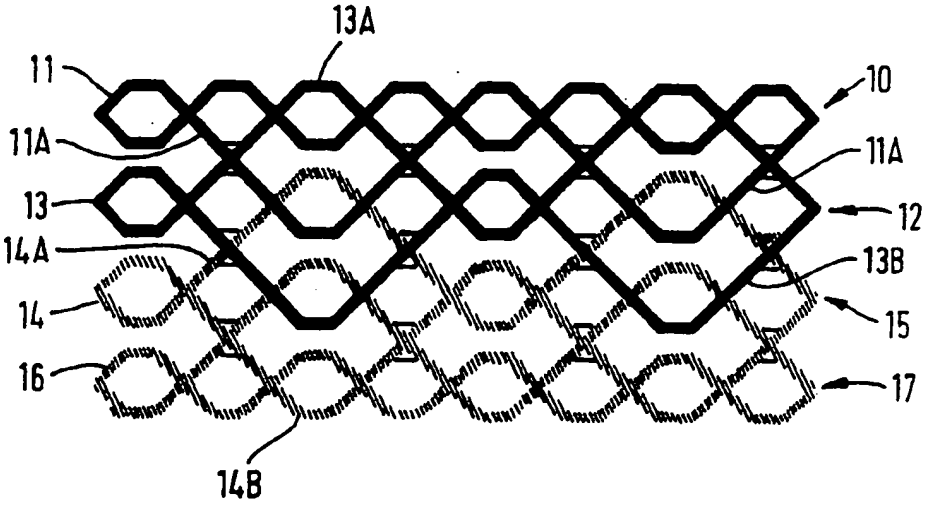


FIG. 2

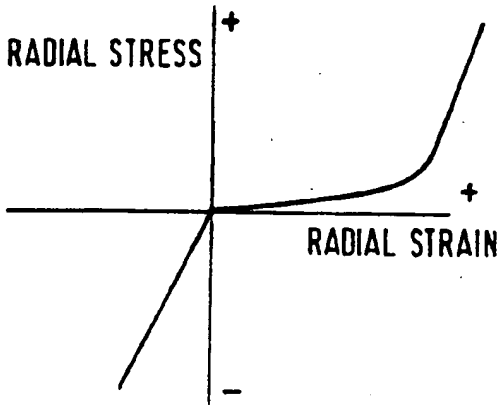


FIG . 3

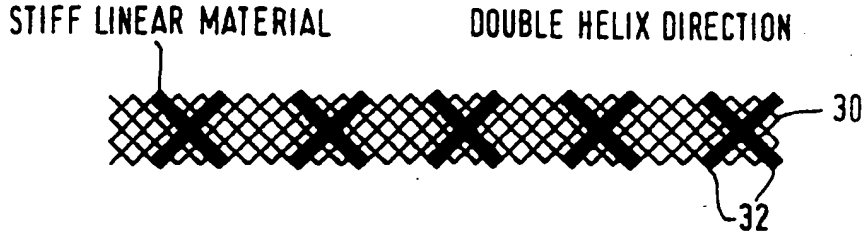


FIG . 4

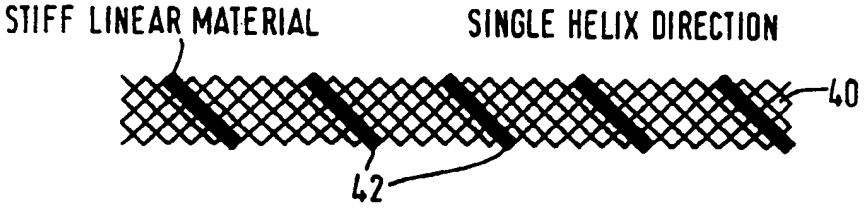


FIG . 11

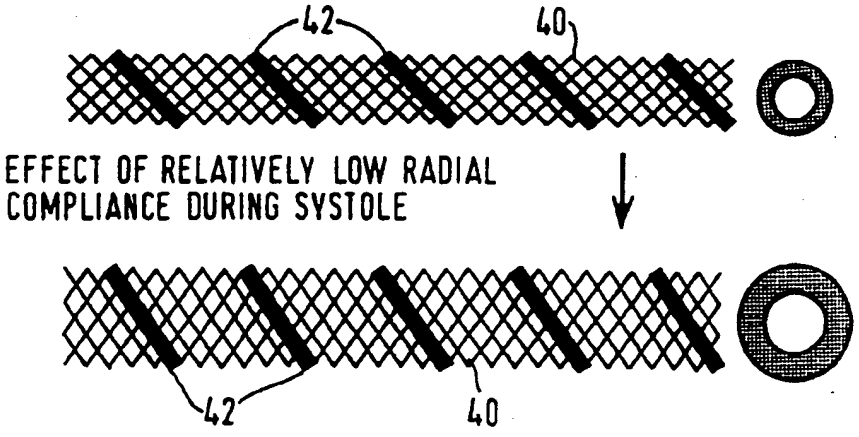
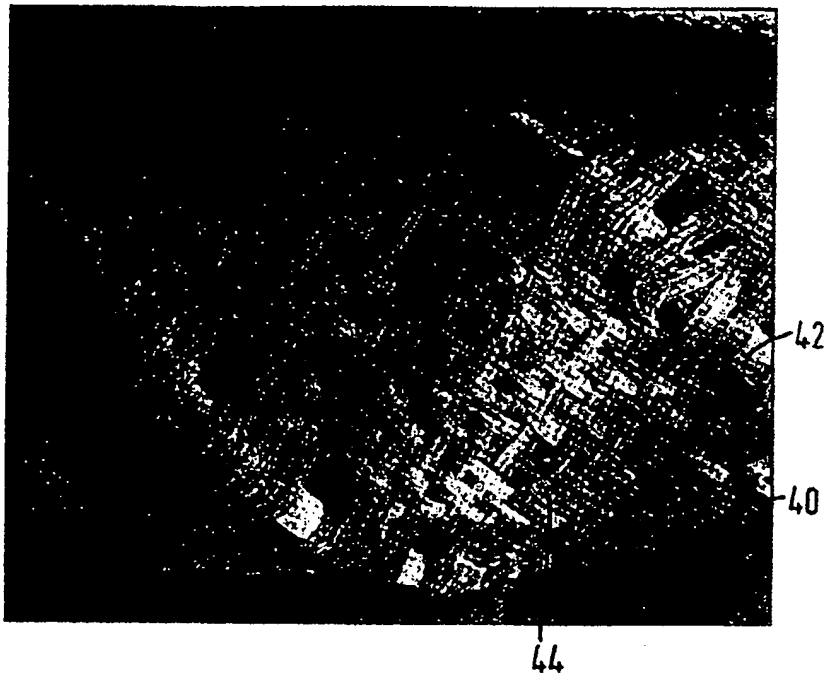


FIG. 5

OUTER SURFACE



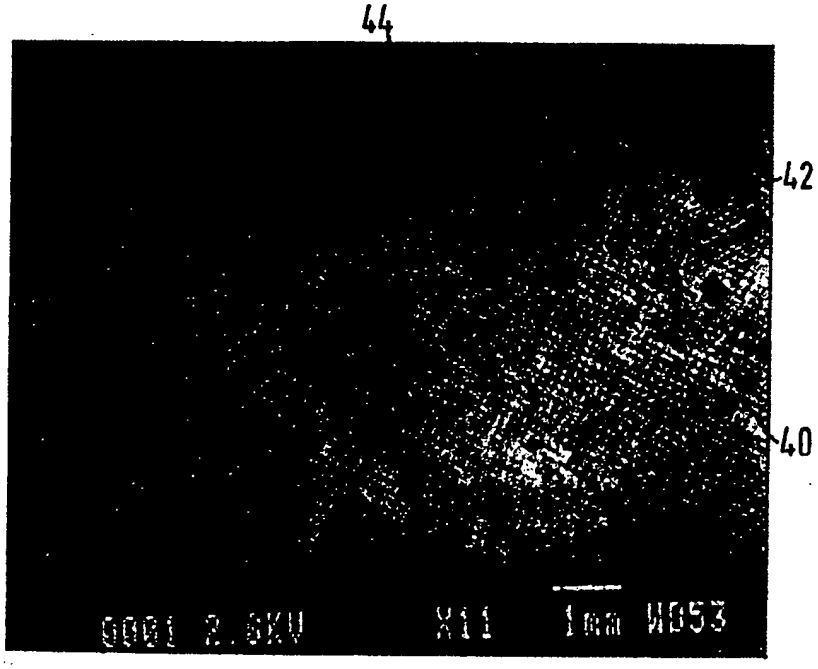


FIG. 6

OUTER SURFACE

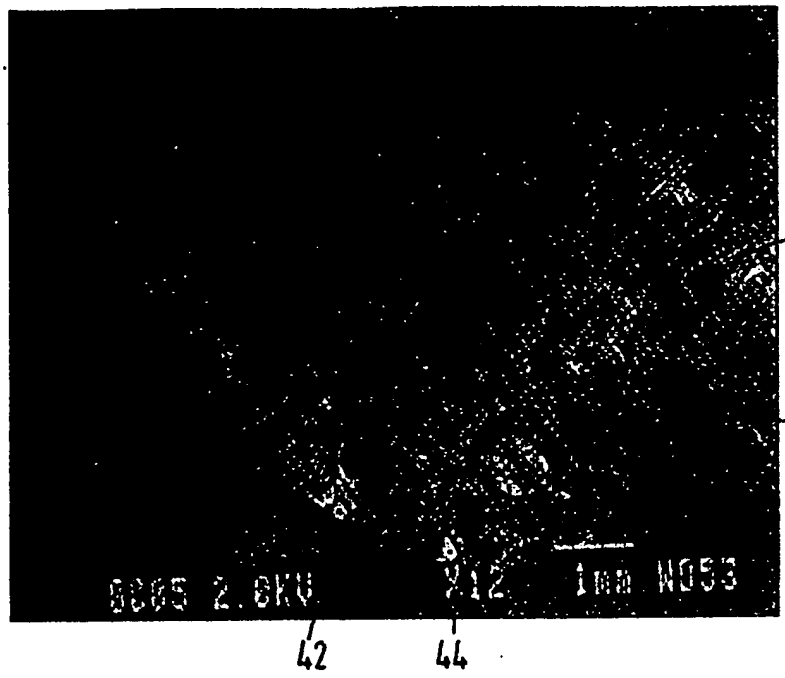


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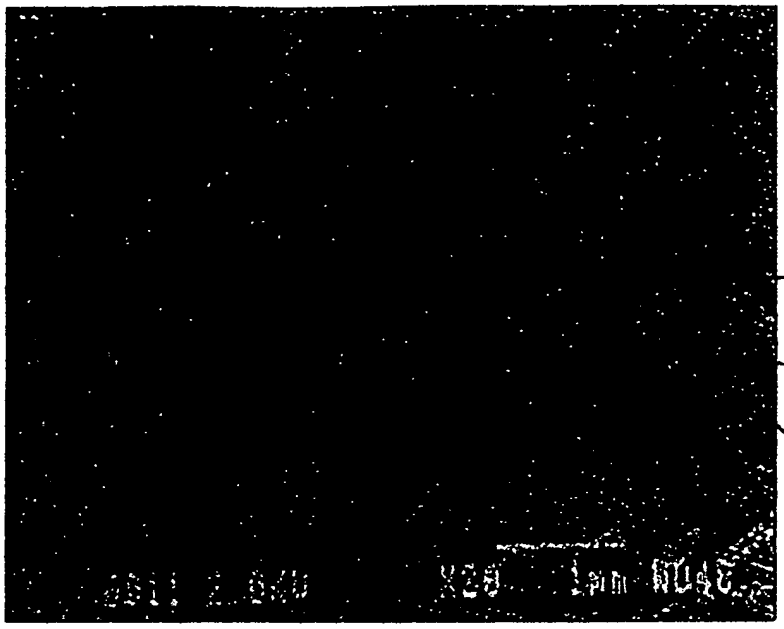
FIG. 7

INNER SURFACE



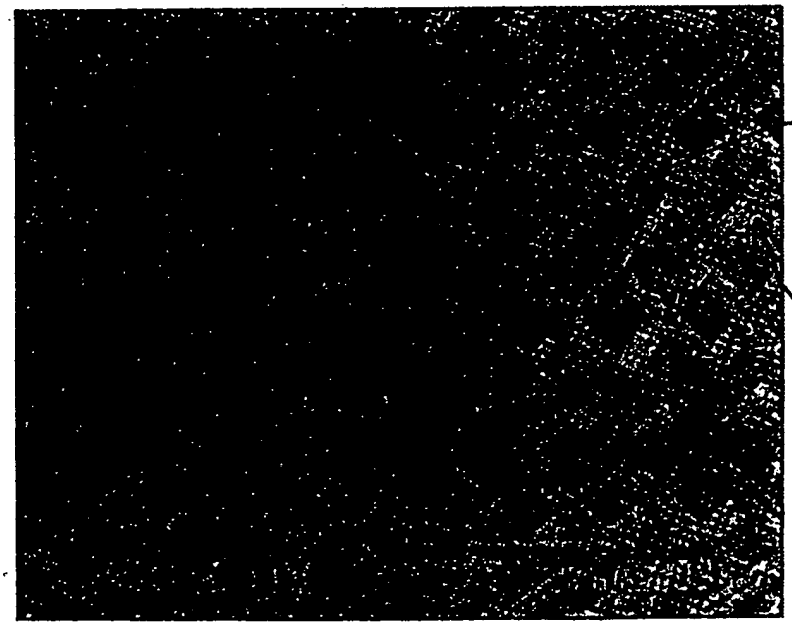
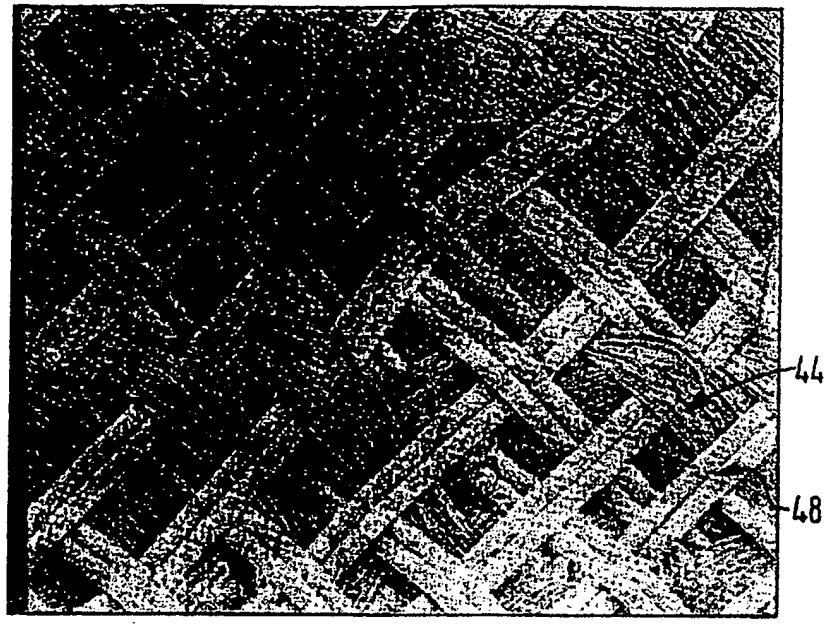


FIG. 8

INNER SURFACE



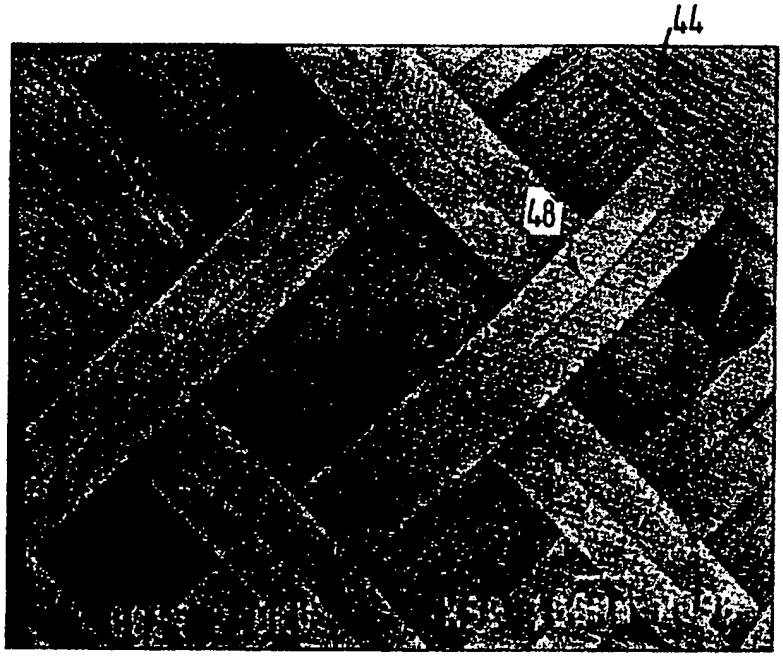
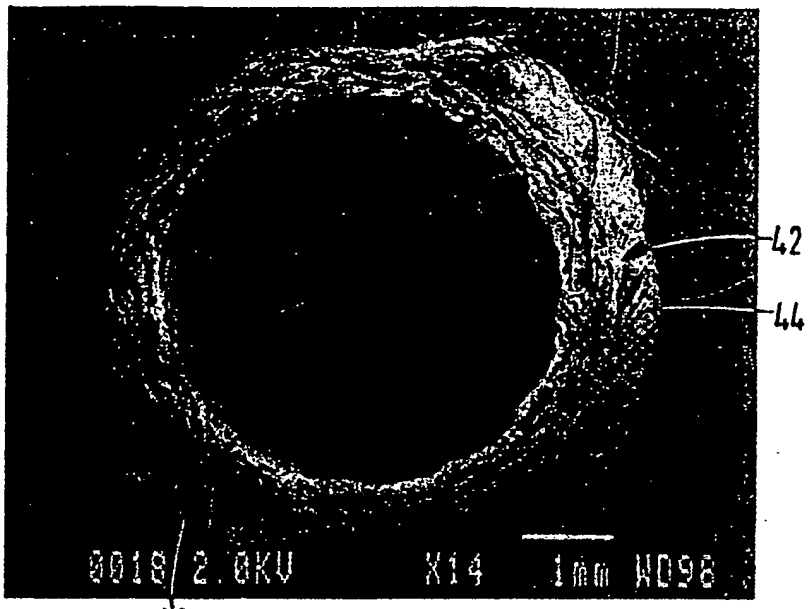


FIG. 9

CROSS SECTION



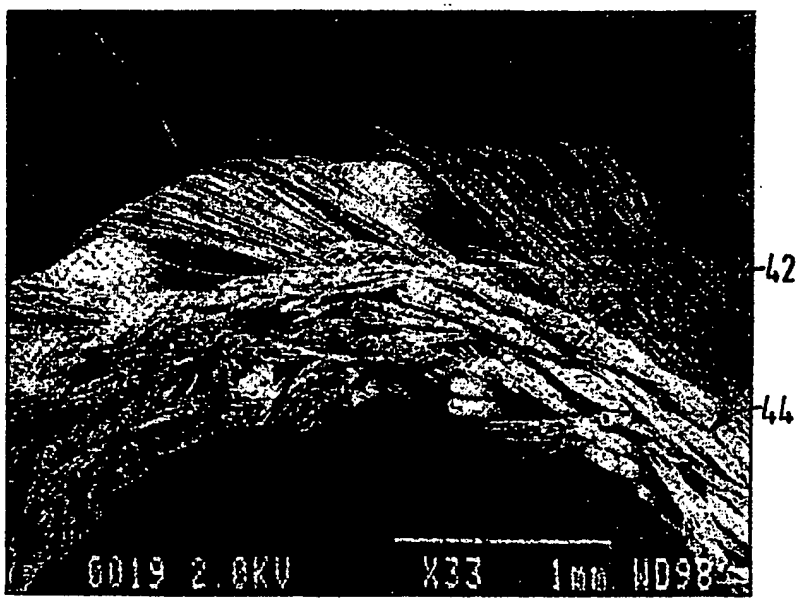
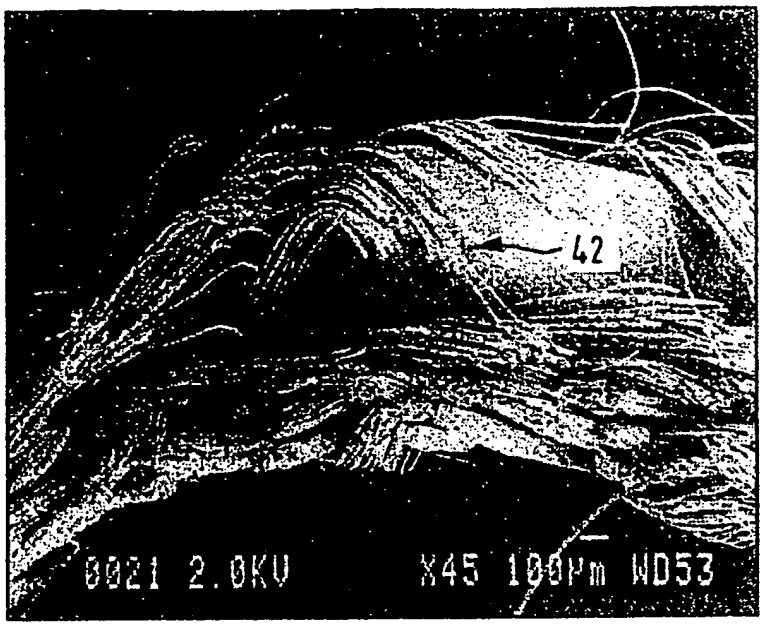


FIG. 10

CROSS SECTION



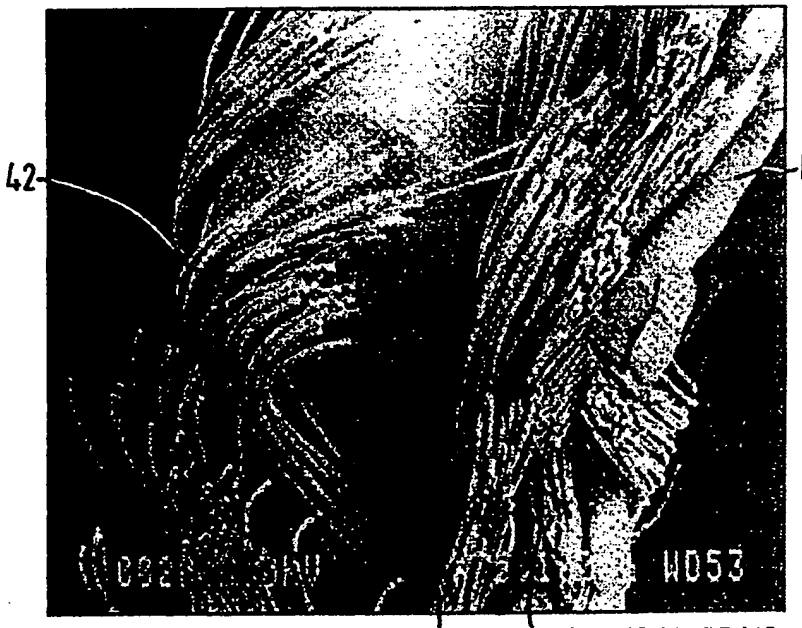
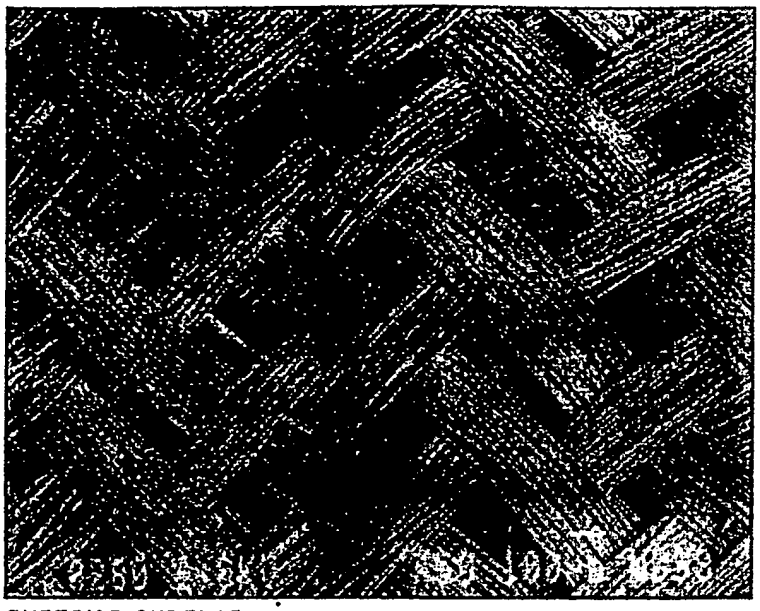
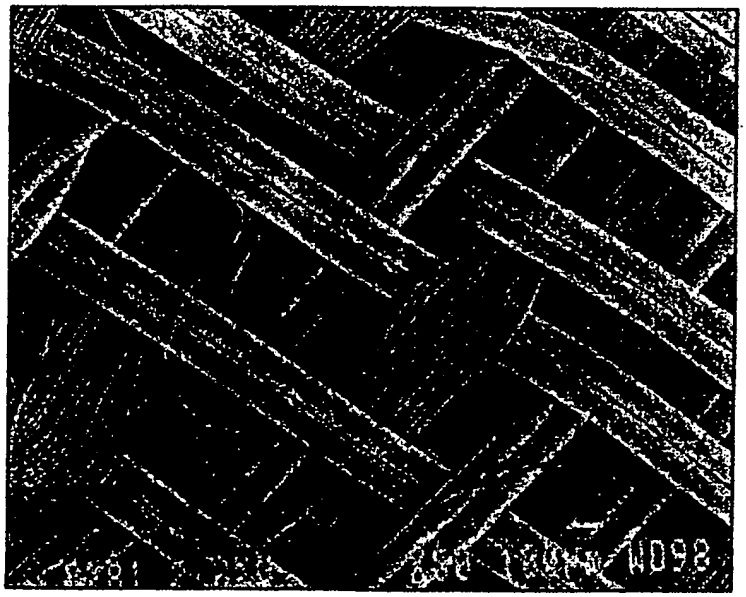


FIG . 12



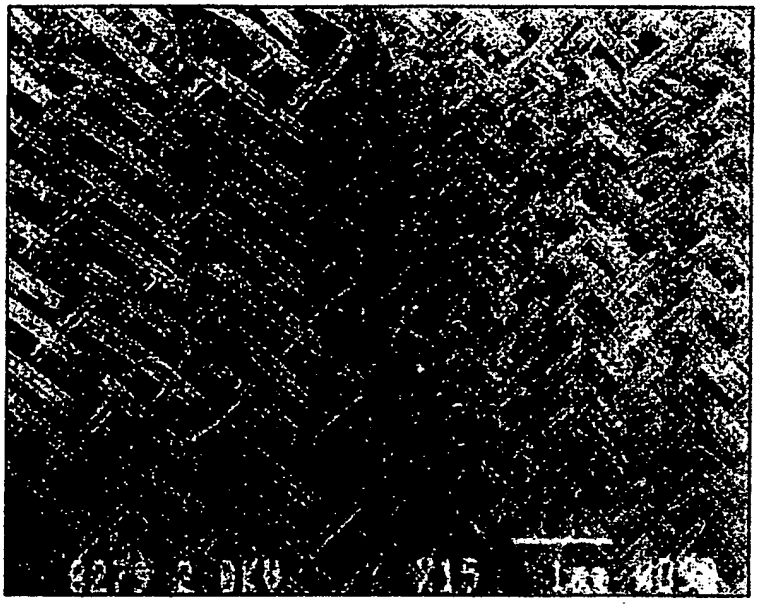
EXTERIOR SURFACE

FIG . 13



INTERIOR SURFACE

FIG. 14



EXTERIOR SURFACE INTERIOR SURFACE

FIG. 15(a)

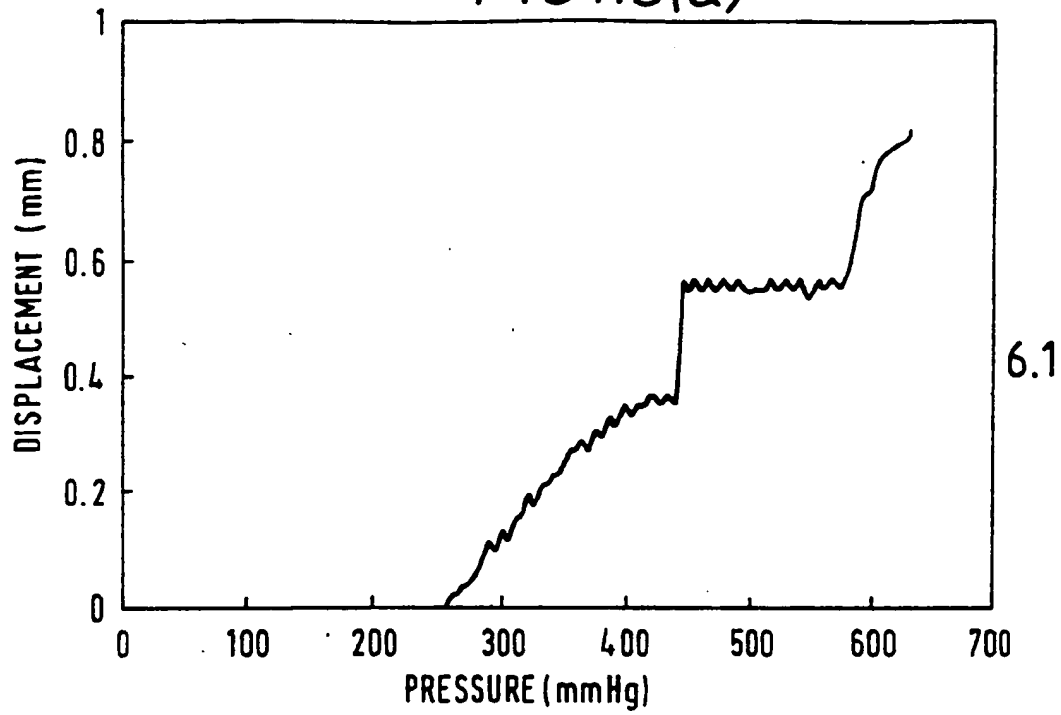


FIG. 15(b)

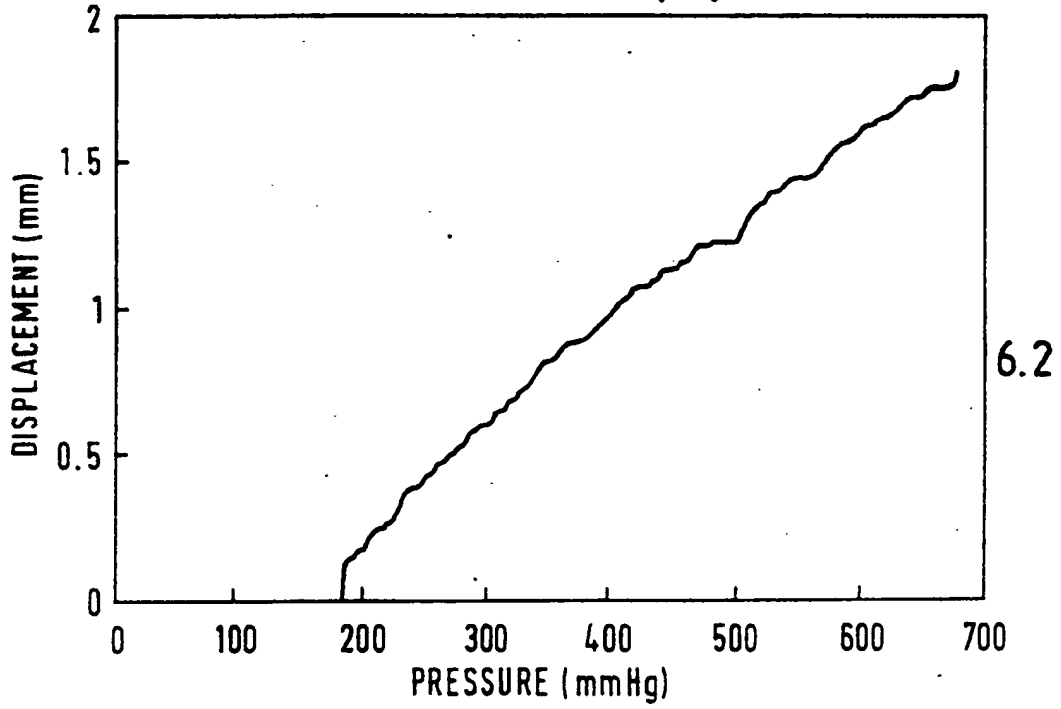


FIG. 15(c)

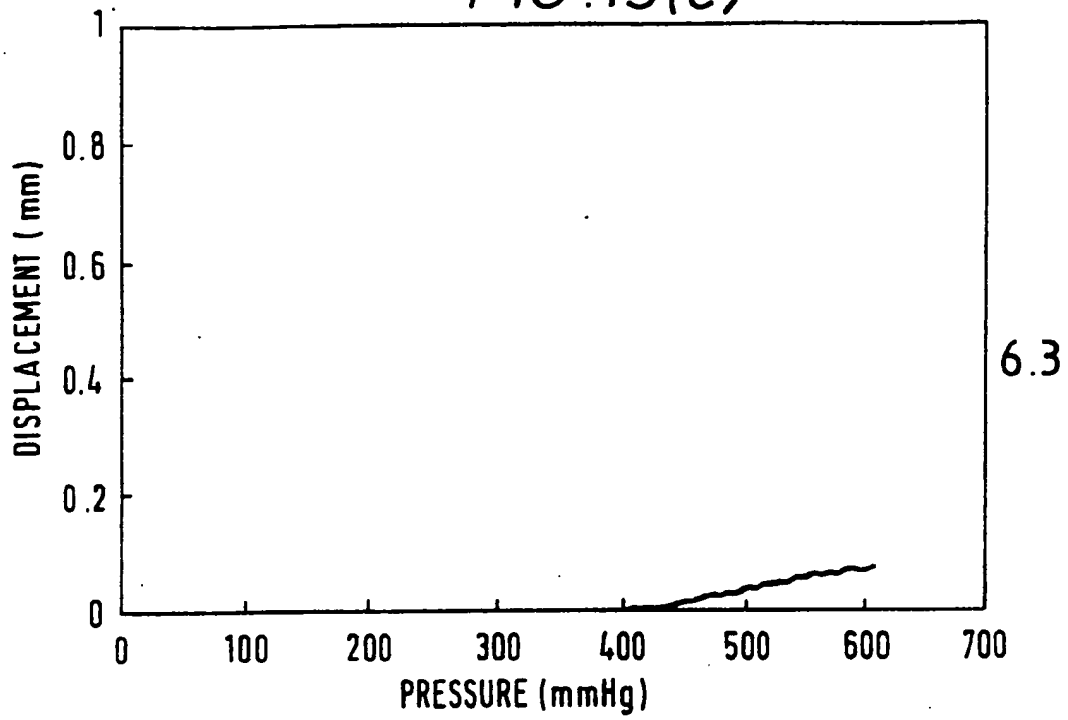


FIG. 15(d)

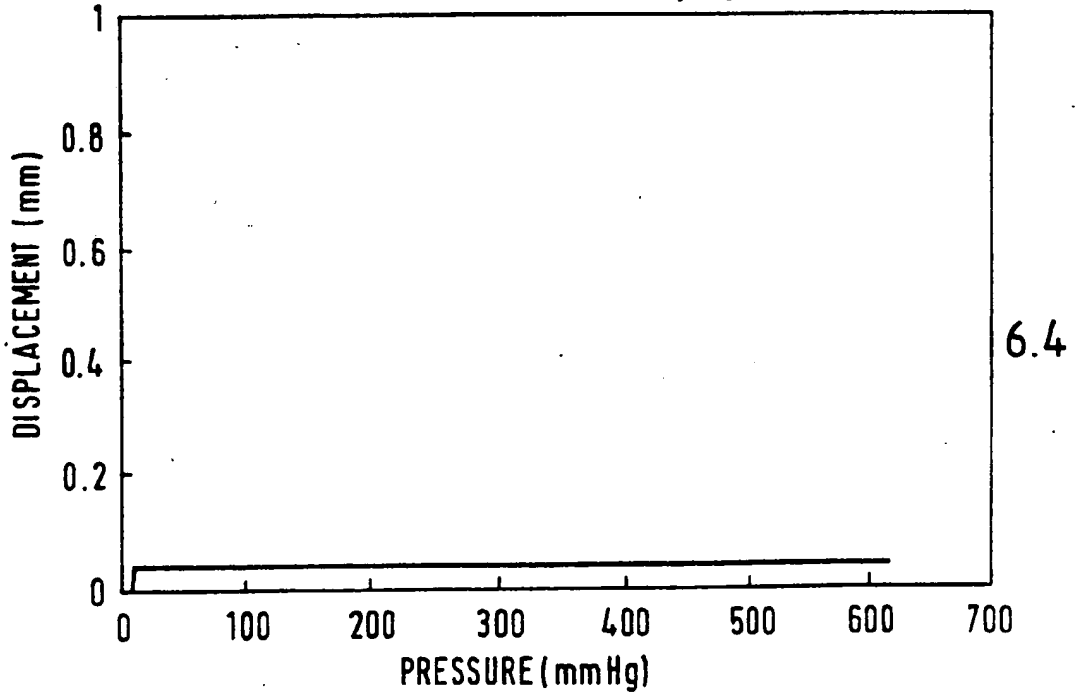


FIG. 15(e)

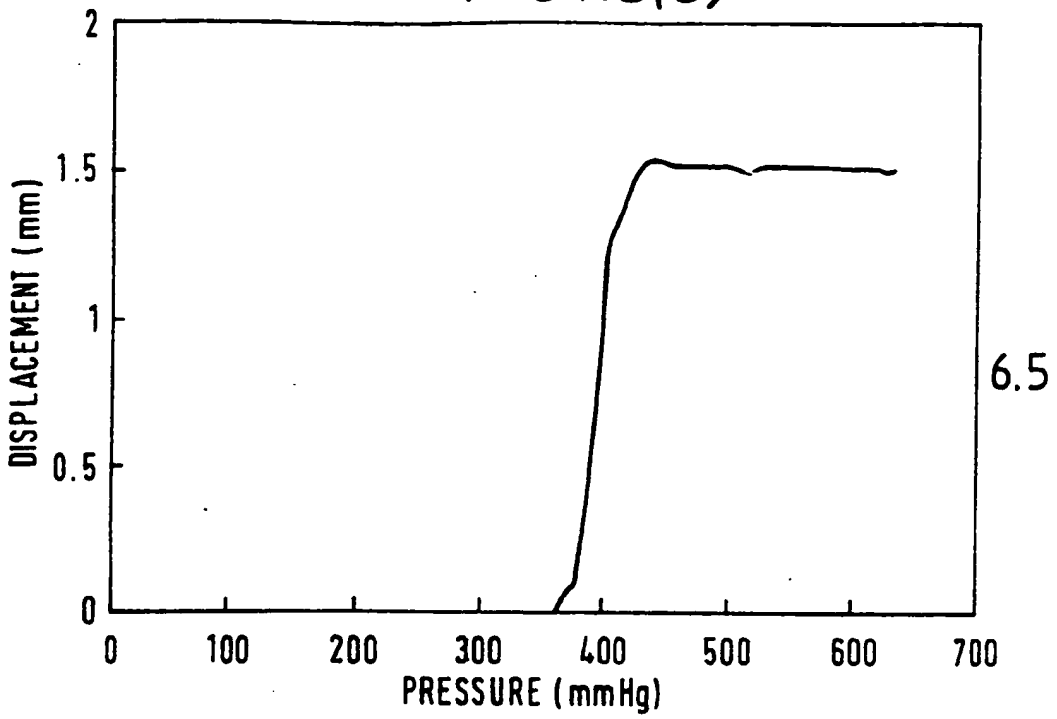
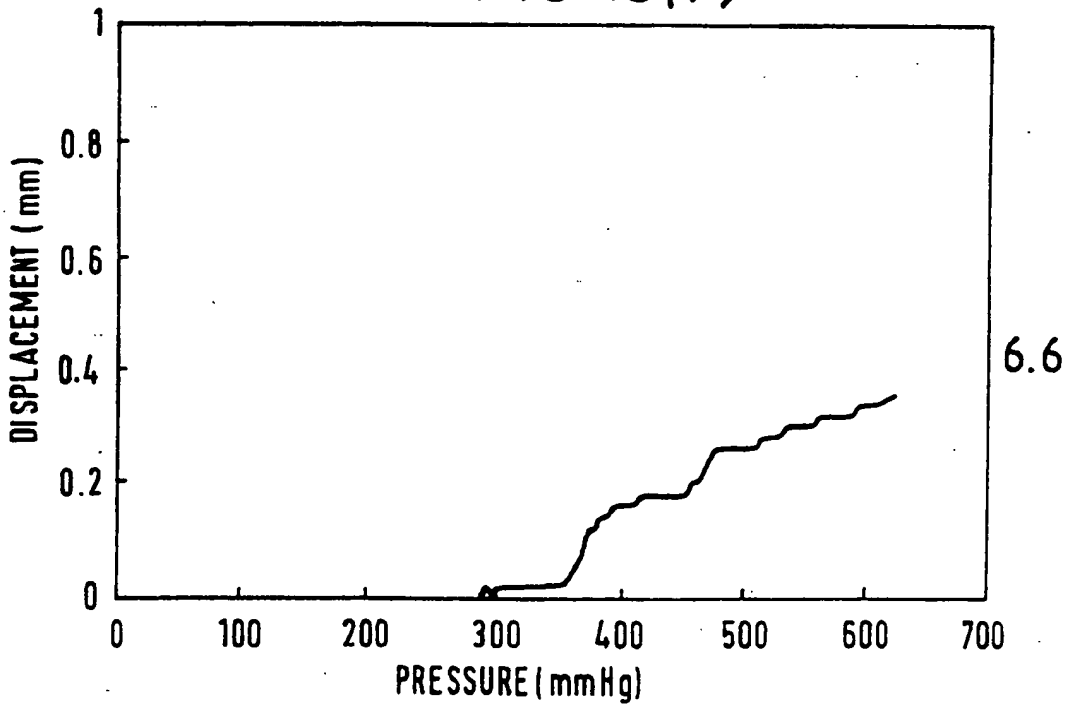


FIG. 15(f)



INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 92/00538

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61F2/06

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
A	EP,A,0 117 072 (J.&P.COATS) 29 August 1984 see claims 1-3 see page 4, line 25 - line 28; figure	1,4,6-8, 20
P,A	WO,A,9 110 766 (ALBANY INTERNATIONAL) 25 July 1991 cited in the application see the whole document	1,6-7, 21-22
A	WO,A,8 800 813 (ST.JUDE MEDICAL) 11 February 1988 see abstract see page 9, line 28 - page 10, line 2 see page 10, line 12 - line 14 see page 11, line 6 - line 7; figures 3A-3B	9-14,16, 19

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
01 JUNE 1992	22. 06. 92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	NICE P. P. R. Nice

Form PCT/ISA/210 (second sheet) (January 1985)

International Applic[illegible] No

III. DOCUMENTS CONSID[illegible]O BE RELEVANT (CONTINUED FROM THE SECO[illegible]ET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	EP,A,0 397 500 (UNITED STATES SURGICAL) 14 November 1990 cited in the application see claims 1-3,23; figure 1 ---	2,4-6,10

ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. GB 9200538
SA 57741

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The members are as contained in the European Patent Office EDP file on
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0117072	29-08-84	AU-B- 541562	10-01-85
		AU-A- 2354584	26-07-84
		JP-A- 59177043	06-10-84
WO-A-9110766	25-07-91	None	
WO-A-8800813	11-02-88	None	
EP-A-0397500	14-11-90	US-A- 4990158	05-02-91
		CA-A- 2016493	10-11-90

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